K112501

DEC 1 4 2011

Heraeus

510 (k) Summary of safety and effectiveness of the Restorative material "*Venus Pearl*"

(1) **Submitter name**

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Date summary prepared: October, 28, 2011

(2) **Name of the device:**

Trade name: "Venus Pearl"
Classification name: Tooth shade material (872.3690)
Product Class: II code EBF

(3) **Substantially equivalence**

Venus Pearl (Project Name SOCO - D 933) is an advanced version of the product Venus Diamond formally NEUN (K073554). The components and their ratio in Venus Diamond and *Venus Pearl* are similar.
The new composite was optimized for anterior restorations appropriate to the soft/creamy consistency demand. The intended use of Venus Pearl is identical to the approved dental composite Venus Diamond.
Venus Pearl is substantially equivalent to the product Filtek Supreme Ultra (K083610).

(4) **Description of the device**

Venus Pearl is a, universal light-curing, radio-opaque nano-hybrid composite for anterior and posterior use. Due to the excellent material properties, a beautiful aesthetic result and a durable, high lustre polish is easily reached.
Nano hybrid composite contain a blend of small particle fillers and large particle fillers that create durable and aesthetic restorations. The nano fillers can reduce shrinkage by an increase of the filler content and provide the natural aesthetic appearance.

It is used as a base in Class I –V restorations and can be placed in increments up to 2 mm thickness for Incisal- and Universal shades and special shades, 3 mm for the core-build-up shade and 1 mm for opaque-shades.

Venus Pearl is used following the application of a dentin/enamel adhesive (e.g. iBOND Self Etch and iBOND Total Etch) designed for use with light cured composite restorations.

Venus Pearl is based on 2-Propenoic acid, (octahydro-4,7-methano-1H-indene-5-diyl)bis(methyleneiminocarbonyloxy-2- ,1-ethanediyl)ester (TCD-DI-HEA) and 7,7,9-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl-dimethacrylate (UDMA) (approximately 59% filler by volume, with 58% anorganic filler by volume, Barium aluminium Fluoride glass, pre-polymerized filler and highly discrete nanoparticles . The filler particle size is between 5 nm and 5 µm

Based on the evaluation of the storage stability test the shelf life of Venus *Pearl* when stored according to the recommendation of the manufacturer is claimed with 42 month and fully complies with the requirements of ISO 4049: 2009.

(5) Intended use

Venus Pearl is a composite for anterior and posterior use

The indication of "*Venus Pearl*" is as follows:

- Direct restoration of Class I - V cavities (acc. to G.V. Black)
- Direct composite veneers
- Shape corrections of teeth (i.e. diastemas, congenital defects in teeth etc.)
- Splinting of teeth loosened by trauma or periodontal disease
- Indirect restorations (inlays, veneers)
- Restoration of primary teeth
- Core build-up
- Repairs of porcelain, composite (in combination with an adequate repair system)

(6) Technical Characteristic

Venus Pearl was developed as Universal composite with a soft/creamy consistency based on the development of the composite product Venus Diamond. Both products were planned to be an ideal supplement in a high quality product family of universal composites.

The international standard EN ISO 4049 has defined basic properties for dental composite materials to ensure the clinical effectiveness. The specification of Venus Pearl like the predicate Venus Diamond meets the requirements of the harmonized standard for dental restorative materials of all cavities (type1, class 2, group 1).

The sensitivity to ambient light and depth of cure of *Venus Pearl* are slightly better to provide an additional advantage especially for core-build-up, however the material properties are very close to VENUS Diamond and much higher than defined by the international standard.

(7) Nonclinical- tests

In accordance with the Medical Device Directive 93/42/EWG and national European medical device legislation, any medical device must be evaluated by the legal medical device manufacturer regarding its clinical performance and safety. This includes an evaluation of biocompatibility in accordance with EN ISO 10993-1. Venus Pearl is exclusively used for dental restoration and it can be concluded that there is only contact with mucosa. The duration of contact of Venus Pearl is >30 days. According to this classification, (ISO 10993-1, Table 1) the following tests has been considered:
Cytotoxicity
Sensitization
Irritation
Systemic toxicity
Genotoxicity
with the same results as for Venus Diamond.

On the basis of the test results, the biocompatibility of Venus Pearl in the aforementioned indication was documented in a biocompatibility evaluation report and the benefit/risk-relation has been judged as positive
An allergenic potential towards the uncured test item in predisposed persons cannot be excluded as for Venus Diamond.

(8) Clinical Evaluation

In accordance with the medical Device directive 93/42/EWG and national European medical device legislation, any medical device is requested to be evaluated by the legal medical device manufacturer regarding its clinical performance and safety. This includes a clinical evaluation in accordance with MEDDEV 2.7.1., which is intended to critically evaluate the clinical benefits of the medical device in comparison to its potential risks. Therefore, any clinical evaluation is part of the compulsory risk management process according to EN ISO 14971, and critical findings must further be considered in the current risk management process of the medical device manufacturer responsible for the evaluated device.

On this background, the clinical evaluation was performed in order to comply with the current European medical device legislation, in particular with MEDDEV 2.7.1. This critical evaluation followed the procedures outlined in the corresponding clinical evaluation report.

Venus Pearl is a Restorative material, light curing, which is generally classified as a class II medical device under the Medical Device Directive 93/42/EEC. Venus Pearl represents a well-known type of restorative material which has proven to exhibit the expected performance and clinical effectiveness. There is no hint for unbearable undesirable effects and potential risks when Venus pearl is applied according to the instruction for use as with Venus Diamond. Considering the evaluated scientific data and technical results for *Venus Pearl* it is concluded that the product can be expected to exhibit the claimed technical performance and those potential undesirable clinical effects and risks seem well controlled and acceptable, when weighed against their benefits in dentistry. Therefore, a positive benefit versus risk ratio can be stated for *Venus Pearl,* provided that the product applied in accordance with its intended use according to the manufacturer´s instruction for use. Nevertheless, a risk for allergic potential towards the uncured Venus Pearl in predisposed persons cannot be excluded as with Venus Diamond.

(9) Conclusion

The risk potential of *Venus Pearl* was proved. All properties of the product were verified successfully.

The biological compatibility of Venus Pearl was investigated to evaluate the toxicological risk. A biological evaluation report has confirmed that the product meets the requirements of ISO 10993 standard. The results were discussed in the biological evaluation report and the benefit/risk relation has been judged as positive.

The physical properties of Venus Pearl were determined in accordance with ISO 4049. All properties comply with and exceed the requirements of this standard. This is stated in section (4).

Based on the results of the clinical evaluation report it is concluded that the product can be expected to exhibit the claimed technical performance and that potential undesirable clinical effects and risks seem well controlled and acceptable when weighed against their benefits in dentistry.

The risk analysis according ISO 14971 was carried out for Venus Pearl and showed the application of the product according to the manufacturer´s instruction for use is considered as safe.

Venus Pearl meets all requirements relevant for dental restorative, light curing material in accordance with the Medical Device directive 93/42/EWG and national European medical device legislation. Based on the actual facts *Venus Pearl* is considered to be effective and safe as the predicate Venus Diamond when used with the manufacturer´s instruction for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Cheryl Zimmerman
Director, Quality Assurance & Regulatory Affairs
Heraeus Kulzer, LLC
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South Bend, Indiana 46614

DEC 14 2011

Re: K112501
Trade/Device Name: Venus Pearl
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: November 8, 2011
Received: November 10, 2011

Dear Ms. Zimmerman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

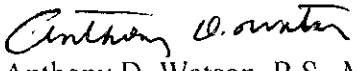
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): __K112501_____

Device Name: Venus Pearl

Indications for use:

- Direct restoration of Class I - V cavities (acc. to G.V. Black)
- Direct composite veneers
- Shape corrections of teeth (i.e. diastemas, congenital defects in teeth etc.)
- Splinting of teeth loosened by trauma or periodontal disease
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- Restoration of primary teeth
- Core build-up
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Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112501